A Cross-Sectional Study of the Impact of Positive Affect on Human Immunity through Cognitive Behavioural Therapy (CBT)

A

SYNOPSIS

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SECTION-I

Introduction

Across evolutionary years of clinical research evidence has compelled that psychological elements (such as stress, clinical depression, and mental disorders) are associated with systematic stimulation and regulation of the immune system and its functions. The systematic stimulation by emotional components results in a number of adaptive and maladaptive immunological responses. Therefore, into various corresponding levels of modulation. Stress or depression is the characteristic responses of the interaction between individuals and the stimuli. On the contrary, the immune response is the “tool” used by the body to connect with the outer environmental factors. Emerging evidence shows that these two frameworks share similar functions, therefore impacting each other.

The capacity to battle against the environmental threats, for instance, calamitous occasions have enhanced endurance parallelly regenerative abilities, and physiological responses maintaining reactions that could improve the endurance. In vertebrates (especially mammalians), such responses consolidate changes which could improve the pace of articulation of oxygen and glucose to the cardiac and involuntary muscles in the body, extending the physiological support for adaptive responses such as "freeze-fright-flight or fight response." Immune responses to stressors may be significant for these adaptive responses on the grounds of the danger associated with the particular situation, combating and escaping responses generally imply the conceivable danger of having injury and may result into the passage of antigens into the circulatory and integumentary system. In line, the cascade of events is initiated by the fluctuated levels of stressful emotional responses or stressors that can activate the stress response system as immune system’s defensive function. The distressful events (clinical stress or chronic stress-negative stress), then can result into the suppressed immune responses, or in-contrast eustress (positive stress) can up regulate immune reaction. Thus, various psychological mechanisms can balance the functional capacity of immune system of an individual.

Any pathology in the skin might contain pathogenic microorganisms that could imitate and cause sepsis (Williams and Leaper, 1998). Changes stimulated by the affect in the immune system could pace up the cascade of healing and aid with guarding off contaminations upholding the immune system. Such changes would be adaptive in nature, alongside the organic bodily changes that could

assist in expanding the evolutionary wellbeing of living beings. Individuals of modern eras seldom experience stimuli that evoked instinctive responses of “freeze-fright-flight-fight” for their lineages, for example, extreme environment without safety measures. Regardless, human physiological reactions continue to mirror the requirements of prior natural conditions. Risk/dangers that does not need an actual organic response (e.g., academic tests) may in this way, experience organic outcomes; from there on affecting the immune system.

Decades of research has provided evidence that various psychological factors (i.e., affect) have a huge impact over the immune system which systematically stimulate it to give positive or negative responses and can time to time show several levels of modulations. These modulations or responses may enhance or may adversely affect the immune function of an individual. An interdisciplinary approach studies the integrational relationship between various physical systems and the modulations and their associated responses, known to be **Psycho- neuro-endocrine-immunology (PNEI).** The interacting disciplines majorly includes psychology, endocrinology, neurology and immunology, extended to psychiatry, behavioral science, physiology, modern medicine, and rheumatology. The main interest of psychoneuroimmunology is to study the interrelation between the nervous and immune system with regards to psychological systems.

SECTION-II

Background and Conceptual framework

The revolutionary article by Solomon (1964) - ***“Emotions, Immunity and Disease-A Speculative Theoretical Interpretation”-*** pioneered the concept of “***Affective Immunology***” in scientific world. The article attempted to discuss about the theoretical foundation of the integrational relationship between the psychological factors (stress and affect or emotion); immune function and dysfunction and has coined the term “**Psychoimmunology**” for affective immunology. Regardless of this significant theoretical paper, only handful of human research have been conducted till the date. However, ensuing exponential growth in the human research has provided evidence of existing psychologically mediated immune responses and modulations in them.

2.1 The Affect (Emotion)-

Affect is a perplexing, variable and is considered as a cyclic process. The expression "affect" is

interpretation of the Latin term "affectus", which can be deciphered as "passion" or "emotion." Rorty (1980) has shown that there are historically recorded changes in the scientific categorizations of the key feelings, affects, wants, or desires, and passion; these are the terms that are utilized interchangeably in shifting interpretations from Greek and Latin until the late nineteenth and twentieth centuries, when "passion" got reserved for sexual roles and genuine responsibility, and "want or desire" was isolated from "affect". However, similar terms-love or like, lust, hate or dislike, outrage or anger, jealousy or envy, disgrace, or guilt- proceed in proof from antiquated occasions to the present; they are found in old Greek scientific taxonomies of the emotions, before that in Egyptian and Hebrew arrangements of demons, and proceed through to Freud (1957) and after.

The primary philosophical text of the subject- Aristotle's Rhetoric (1991) coordinated the affects regarding "grace and disgrace, love and contempt, fear and confidence, shame and respect, graciousness and heartlessness, pity and ire, jealousy and emulations. Present definitions of the affect or emotion stem primarily from Darwin's physiological record of the emotion and is referred to as the William James-Carl Lange theory. In their theory, James (1884) & Lange (1885) has principally directed that physiological state leads to affective states. This is notably provided by simulations, for example, "crying make us sad," in spite of the fact that for William James the issue was undeniably more nuanced. It was mistaken that there were genuine contrasts among James and Lange, particularly concerning James' familiarity with the external variables impacting the emotional state while Lange reinterpreted the theory by operationalizing it.

Affect has been hypothesized in two prevailing perspectives. The primary viewpoint, has its foundations in psychology and neuroscience, inclined to view **“Affect as an elemental state”.** Subsequently, this practice is reflected in Tomkins' theory (1982) of *primary affects* and Damasio's (1999) theory of *basic emotions*. Ongoing expansions on this practice incorporate the work by Brennan (2004). The subsequent point of view is commonly associated with advancements in field of philosophy, human behaviour and the humanities, regards **“Affect as an Intensive Force”**. This practice is evident in Massumi's (2002; 2015) theory of *autonomous affects* and Thrift's (2008) *non-representational theory*, whose most well-known supporter is Deleuze (1988).

2.2 The Immune System-

The immune system revelations, initially were strengthened by a desire to prevent the spread of infection and grow better therapies for the incapacitated individuals. The immune system is represented as a physiological arrangement of resistance. Term "immune," is derived from the Latin word "in" and "- munia," signifies "not committed to support or not obligated to service." Roman residents, especially male people were obliged to participate in specific obligations related with the state. The immune individuals were excluded from this service. At that point, to be immune intends to be liberated from what is viewed as a characteristic outcome of associating with something that could be greater than oneself. For the individual life form, to be essential for the universally accepted articulation of Life, an individual should be exposed to the potential for harm for their efficient survival. Thus, immune is the condition where an individual is away from the potential natural consequences of vulnerability. Therefore, the immune system is an arrangement of protection rather than array of resistance. More precisely, it manages and directs the behavioral responses related to self-versus non-self-elements, friend versus antagonist elements of behaviour, which subordinate four essential immune functions: vigilance, resistance, protection, and attack.

In the subsequent time, the requisite for the immune system emergence has resulted out of the necessity of exposing every closed system to its surroundings. The immune system is a perplexing organization of innate and adaptive immunity including both humoral or fluid and cellular parts. This isn't essential for a "super-system" yet a receptive methodology utilized by the integrated complex of neural and endocrinal system, as the administrator for effective functioning; thereby, managing the structure and function of the system and showing receptiveness to hepato-pancreatic competency. Moving towards immunity from a comprehensive systems viewpoint, it offers a more noteworthy complexity and scope to the assessment and treatment of ailments.

2.3 Association of Affect (Emotion), Immune and Other Physical Systems-

Psychological factors are identified as underpinning the immune function of an individual. Emotions and immune processes are interlinked in such a manner that they can be followed back to relics. However, the rational of mechanisms underlying these processes have recently been revealed, greatly due to the investigation of Selye (1976) and his associates. They have showed

that the pituitary gland and the hypothalamus plays a vital role in controlling the release of stress hormones, specifically the glucocorticoids, which help the body to regulate with external and internal stressors but moreover have a role in regulating immune functions. Consequently, it was revealed that the immune transmitters, the cytokines, and concerned secretory Components from immune cells can interconnect with the endocrinal and central nervous systems to modulate their functional capacities. It is currently perceived that the endocrinal-Immune system and the brain are functionally linked to give an organized reaction to external and internal stressors. This network is additionally connected to the central and peripheral supportive systems, thereby giving a structure whereby the nervous system can precisely influence the function of the Immune system by stimulating adrenoceptors that are situated on immune cells. Affective immunology also termed as Psycho-neuro-endocrine-immunology has developed into an exceptional discipline for studying the psycho-immune-endocrine-neuro-behavioral network in depth.

In the course of recent years, evidence have accumulated on the nature of the interactions between the central sympathetic and the immune system. This Immune system is auto regulated, that is, immune cells recognize normal cells as the cells that belongs to the body of a particular person from foreign (unknown to a person's body) cells so that escalating an immune reaction against antigens does not need a significant involvement from the cerebrum. Nonetheless, it is evident that the cerebrum plays a significant role in regulating the function of the immune system and, on the other hand, the immune system plays a vital role in the symptoms of patients experiencing major mental disorders such as schizophrenia, depression, and anxiety disorders. Thus, in the broad view the Immune system is principally an auto regulated procedure which concern about protection of the body counter to irresistible illnesses, it is currently evident that there is consistent 'cross-talk' between the psychological, endocrine, immune, and neural system.

2.4 The Crosstalk between Emotional Responses and Immunological Responses-

Emotional reactions are elements of complex interactions of body functions that influence ability of the human body, either to stay in healthy state or to be protected or to confront ailment or to fight infection. Health improving and health hindering practices, comprising diet, sedentary lifestyle,

exercise or physical activeness, smoking, and protection from exposure to harmful ecological elements can compromise health or profit health. It is evident that inherited and behavioral factors are integrated with health, in compound ways proceed to mount, and information about these impacts has consequences for clinical (psychiatric) results and essential health care routine. Evidence through experiments is yet conflicting however, data collected from investigations of health and behaviour recommends that an individuals' emotional states impact the aetiology and progression of infection and additionally to have endurance or vulnerability to disease.

Generally, psychological or behaviour factors exerts their impact on health or ailment in three essential manners- direct biological changes, genetic factor-based impacts and environmental factor-based modulations (Rowe 2001). The findings from the experiment of Kiecolt-Glaser et. al. (1994), has been revealed that stress results in elevation in level of blood pressure, sympathetic stimulation and heart rate, and is also related with changes hematological values contributing precisely to hypertension, coronary disorders, or cardiac events. Regardless of whether the immune system changes are strong or weak enough to heighten susceptibility towards infection or ailment isn't clear, however they have been ensnared in the causative factors and wound recovering, progression of viral infections and malignant growth. (Kiecolt-Glaser et. al., 1994)

Watanuki and Kim (2005) were engaged in smartly devised research on the physical and functional responses stimulated by pleasurable inducements. Results of the research studied various physiological responses of the central nervous system, immune system, endocrine system, and autonomic nervous system when pleasant stimulus, like smells, expressive images were presented to subjects of the study. The outcomes uncovered that electroencephalogram movements of the left frontal cortex were improved by a pleasing odour, thereby affecting positive emotions and an increased level of secretory immunoglobulin-A and linguistic pleasant emotion were induces a decreased level of salivary cortisol. Various systems were found to be associated with the introduction of pleasant emotions and are induced by central nervous system self-stimulus and especially the inducement system. Structurally the central brain position strongly related with the inducement system is in the middle of forebrain bundle. The amygdala complex shows complexly linked fibre networks with the inducement system and results into the input and output of the system. Subsequently, the amygdala performs the role as

the centre for coordinating pleasant emotions. The amygdala separates all sensory system of tangible inputs and distinguishes stimuli significant for the body while the hypothalamus plays a vital role in emotional articulation.

At the point when corticotrophin releasing hormones are emitted from the nerve centre (hypothalamus), catecholamines and cortisol are next to be discharged from the adrenal glands via pituitary glands, both secretions are from the hypothalamus-pituitary–adrenal and sympathetic adrenomedullary axes. Functioning of the pituitary–adrenal- hypothalamus system can be observed by the salivary cortisol levels, while those of the sympathetic adrenomedullary system can be assessed by the functioning of heart. As secretory immunoglobulin, a parameter of immune systems' action is strongly related with pituitary–adrenal-hypothalamus systems, its levels should be also estimated time to time. The innovative examination by Watanuki and Kim (2005) focused on the impacts of pleasant feelings activated by visual, linguistic and olfactory stimuli on functional response of body.

It is evidently perceived that the stress has a significantly greater impact on the immune system through characteristic emotional and/or behavioral manifestations, including anxiety, stress, outrage, fear and anger and major physiological changes such as pulse, blood pressure, and perspiration (Chrousos et. al., 1992). Investigators have proposed that these progressions are advantageous to the body only if they are for a short span of time; however, when stress is persistent, the body system becomes incompetent to sustain equilibrium state or homeostasis and the body shows the prolonged state of excitement, where digestion is observed being slower than usual to reactivate or rather does not participate in the reactivation appropriately, resulting into heartburn. Furthermore, blood pressure continues to elevate. (Chapman et. al., 2010).

Decades of research have revealed that the meta-analysis has shown a consistent immune dysregulation in healthy individuals undergoing the acute/ chronic stress conditions. In the first phase of meta-analysis performed by Herbert and Cohen (1993), observed 38 studies of distressing events and immune system in healthy individuals. The study included investigations of consistent laboratory stressors such as speech or linguistic task and momentary naturalistic stressors like clinical examinations, and long-term naturalistic stressors such as separation, deprivation, caregiving, and unemployment. The findings have revealed that stress-related components have increased in the

number of white blood cells, furthermore, decrease in the number of the antigen representing cells such as T-helper lymphocytes ($CD4^+$), T-cytotoxic lymphocytes ($CD8^+$), T-suppressor/ regulatory lymphocytes (T_{reg} cells), B-cells, Natural Killer lymphocytes (NK). It also observed the stress-related declines in number of Natural Killer cells and stress-related inability to restore the immune functions in the studied individuals. These impacts were predictable for short and long-term naturalistic stressors; however, no similar results were obtained in the case of laboratory stressors.

Zorrilla et al. (2001) successfully replicated Herbert and Cohen's (1993) first phase of meta-analysis. They utilized similar research design and selection procedures as of Herbert and Cohen and they explored 75 results related to stressors and human immunity. Naturalistic stressors were related with increase in number of circulating neutrophils and decrease in number and percentages of total T-cells and helper T-cells, Natural Killer (NK) cells and cytotoxic T-cell lymphocytes.

2.5 Enhancing the Positive Affect by Cognitive Behavioural Therapy

Despite of the conceivable detrimental impact of stress on person, scarcely any interventions are accessible for those confronting difficulties due to stress or stress-related uneasiness, outrage, or worry. Cognitive Behavioural Therapy (CBT) has been investigated within the context of health and immunity and exploration has demonstrated the possible methods that CBT can be effective in targeting the antecedents and behaviour and impact its consequences in positive manner. CBT is evidently an efficient technique based on the premise that the behaviours that are counter- productive or harmful in their nature are often result of the maladaptive thinking pattern. The objective of the intervention is to distinguish and modify these maladaptive thinking patterns by encouraging insight to the therapy and providing the thought management skills. Since its development, it has been used to treat a large number of conditions, for example, sorrow, uneasiness, over the top impulsive issue, bulimia nervosa, outrage, and constant torment. It has been widely explored and laid out as a key device in mental treatment.

Cognitive Behavioral Therapy (CBT) is a form of psychotherapy that focuses on the role of cognition in the expression of emotions and behaviors. Cognitive behavioural therapy (CBT) is a method that aims to reduce psychological distress and dysfunction by exploring and addressing how the integration

of service users' thoughts, feelings and behaviours are contributing to the presenting problem. Three assumptions form the foundation of CBT:

1. Thinking (cognition) mediates emotions and behaviours;
2. Faulty cognitions lead to psychological distress and dysfunction;
3. Psychological distress and dysfunction is reduced or alleviated through modifications in the faulty cognitions and behaviours. (Trower et al, 1988; Vonk and Early, 2009).

CBT seeks to modify and replace existing faulty or distorted thoughts, feelings and behaviours with more positive and acceptable ones that will lead to the alleviation of the presenting problem (Teater, 2010). The implementation of CBT in practice involves three stages: assessment; intervention and evaluation (Teater, 2010).

1. Assessment consists of exploring jointly with service users how their thoughts, feelings and behaviours are contributing to the presenting problem in terms of frequency, intensity and duration. The assessment stage will inform the type of intervention to be selected, based on the thoughts, feelings or behaviours that are the focus of change.
2. Interventions could include cognitive restructuring (Frojan-Parga et al, 2009); relaxation techniques (Payne and Donaghy, 2010); social skills training (Sheldon, 1998); assertion training and problem-solving skills (O'Donohue, 2003); systematic desensitization (Sharf, 2012); and reinforcement, modelling and role-plays (Sutton and Barto, 1998).
3. The evaluation stage serves as an opportunity to identify any changes that have occurred in the intensity, frequency and duration of thoughts, feelings and behaviours and the extent to which the presenting problem has diminished from pre- to post-intervention.

Happiness is an important goal for most people (Diener, 2000), and central to the pursuit of this goal are the ways in which people seek out and maintain positive experiences. To investigate the up-regulation of positive emotions—the strategies that people use to create, maintain, and enhance emotions such as joy, contentment, and pride. Broadly, emotion regulation is defined as "the set of processes by which individuals influence which emotions they have, when they have them, and how they experience and express them" (Gross, 1998b). Although people occasionally decrease positive emotions or increase negative ones (Parrott, 1993; Tamir, 2005), the majority of emotion regulation

efforts in life aim to decrease negative or increase positive (Gross, Richards, & John, 2006). In order to elucidate the function that emotion regulation CBT plays as a necessary mechanism to achieve the best outcomes. Researchers are beginning to systematically test whether changes in emotion regulation abilities mediate reductions in symptoms and improvements in psychological functioning and well-being. Modern conceptualizations of psychopathology have increasingly emphasized the role of emotion dysregulation in the onset, maintenance, and exacerbation of psychological disorders (Aldao, Nolen-Hoeksema, & Schweizer, 2010; Kring & Sloan, 2009; Linehan, 1993). Thus, contemporary versions of CBT have begun to adopt an emotion regulation framework in treatment.

CBT assumes that maladaptive feelings and behaviors develop through cognitive processes which evolve from interactions with others and experiences in the environment. The goal of therapy is to identify the maladaptive cognitive process and to learn new ways of perceiving and thinking about events. One of the primary goals of CBT is to teach patients to identify, evaluate, and modify their dysfunctional thoughts and beliefs (i.e., cognitive restructuring) through therapeutic techniques such as the Daily Record of Dysfunctional Thinking (i.e., thought record; Beck, 1979).

Additionally, an integral component of CBT is its emphasis on reducing problematic behaviors (i.e., avoidance, social withdrawal) and promoting more functional ones (i.e., through behavioral activation, exposure) (Barlow et al., 2010; Craske & Barlow, 2006; Gilson, Freeman, Yates, & Freeman, 2009; Hope, Heimberg, & Turk, 2010). Critically, CBT teaches patients skills that not only facilitate symptom reduction, but also lead to long-lasting improvements in mental health and reduce the risk of relapse (Hollon et al., 2005; Hollon, Thase, & Markowitz, 2002).

Although CBT was initially developed to treat depression (Beck, 1979), it is now successfully utilized to treat a wide range of additional psychological disorders, including a host of anxiety disorders (e.g., Barlow, 2002; Craske & Barlow, 2006; Hope et al., 2010; Zinbarg, Craske, & Barlow, 2006), eating disorders (Fairburn, Cooper, Shafran, & Terence, 2008), psychotic-spectrum disorders (Tarrier & Taylor, 2008), personality disorders (Linehan, 1993), and attention deficit hyperactivity disorder (ADHD; Safren, Perlman, Sprich, & Otto, 2005), among many other problems (Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012).

SECTION - III

Rationale and Research Methodology

3.1 Need of the study:

Since the emergence of life- human mind and body are considered as the two separated entities. Thus, their associative processes- emotional, mental and physical processes respectively were thought to be unique of each other. The recent studies have illustrated that the emotions and body are intimately intertwined entities rather than being separated from each other. Also, their processes are collaborative in nature and works interactively. The chemistry and biology of a person affects his/ her emotions and other mental processes. With all these factors combined it further impacts the health. Emotions adjust not only the mental but the bodily states. Also, state of mind has long been suspected of having an effect on the human physiological system.

René Descartes in 16th century argued that human mind has a control over human body and its functions through pineal gland, which partially was proven possible. Descartes dissected animals and was first to understand the Mind-Body Interaction, i.e., association of the mind (mental aspects) with body (physiological aspects). Though he believed that "mind is fundamentally different from the mechanical body and its processes, yet they share a strong integrative functional relationship" (Srivastava, 2001). The question of establishing the relationship between mental and physiological aspects of individual has been prominently investigated by numerous philosophers, psychologists, physiologists, and physicians in 18th and 19th century (Fancher & Rutherford, 2011).

In spite of such early perceptions, the possible association seems to have been largely ignored in 20th century, while developing the new science of psychology (Benjamin, 2007). Though, in recent times it is scientifically proven that the mental affect (specifically emotions) manifest in the body as physical sensation as well as awareness of the corresponding bodily changes subsequently may trigger the emotional sensations, and vice-versa. As pointed out by John and Gross (2004), emotions are often helpful, but sometimes (physiologically) destructive. With reference to this issue, two important aspects of emotions need to be disentangled: (i) the subjective experience of emotions per se and (ii) the regulation of these emotions. Among other things, a major challenge is to find ways of regulating one's emotions so that one retains his helpful features while limiting his potentially destructive

aspects. The things a person do before an emotion response has become fully activated determine a person's physiologic and behavioral reactions.

The proposed study will be a modest attempt in gathering statistical and clinical evidence thereafter, filling the gap of knowledge existing between various psychological and physical factors that can influence immune processes in humans and vice-versa. The following points will strengthen the requirement of proposed research.

3.1.1 There is provocative evidence that trait Positive Affect may influence health and well-being. However, Strong inferences are not yet possible. One problem in interpreting this literature is that in many cases it is difficult to distinguish between the effects of positive and negative emotions. Interestingly, people's experiences of positive and negative emotions are partly independent in different circumstances.

3.1.2 Negative affective styles such as anxiety, depression, and hostility have long been accepted as predictors of increased risk for illness and mortality. In contrast, positive affective styles have been relatively ignored in the health literature and research.

3.1.3 Surprisingly, studies that have focused on the effects of negative emotions on health have similarly failed to establish control for positive emotions. Consequently, it is difficult to conclude from the existing literature whether sadness results in a less healthy, shorter life or whether happiness leads to a healthier and longer one.

3.1.4 It is also unclear whether it is important to distinguish among the various subcomponents of Positive Affect, such as happiness, elation, and joy, or whether these affects cluster together in experience or in how they influence health.

3.1.5 There is evidence that the expression of Positive Affect varies across cultures, Majority of the researchers are conducted in Western countries, but it is use of emotions is evident in Indian Context because of heritage, culture, and values. Consequently, it is important to know to what extent positive affect may influence the health in Indian population.

3.1.6 Despite the vast body of knowledge gathered on the links between immune and emotional responses term there have been very few items made to explore the links and their interrelationship

maybe because of perceived impression that the field of immunology and psychology are polar-opposite.

3.1.7 Research in this field will allow better understanding of the immunological basis of mental or psychological disorders and a possible emotional route towards immune diseases.

3.1.8 The voluminous literature is available in this area of study but the researcher has not come across any study which is specially designed to explore the self-regulatory strategies and to enhance the quality of life through individualized intervention strategies for individuals dealing with the psychological aspects affecting the immune function or vice versa.

3.1.9 All the previous studies in this area of effective immunology were restricted to clinical and experimental evidence showing an increased incidence of emotional disorders in the patient suffering from immune diseases and increased susceptibility to immune diseases in patients suffering from mental disorders. On the contrary the molecular and cellular links between emotional and immunological system needs to be explored and can be used in significant advances in the translational research.

3.1.10 Past research provide support for several promising avenues for intervention to prevent stress induced immune dysfunction however for this research is warranted through suitable and appropriate individualized intervention strategies.

3.2 Justification of the problem:

The study of human psychoneuroimmunology is the understanding of the role of psychological factors in physical illness. Initially, it provides psychologically and biologically plausible explanations for how psychological factors influence immunity and immune system–mediated disease. Subsequently, this covers substantial evidence that factors such as stress, negative affect, clinical depression, social support, and repression/denial can influence both cellular and humoral indicators of immune status and function.

In the case of the less serious infectious diseases (colds, influenza, herpes), it considers consistent and convincing evidence of links between stress and negative affect and disease onset and progression. Although still early in its development, research also suggests a role of psychological factors in autoimmune diseases. Evidence for effects of stress, depression, and repression/denial on onset and

progression of chronic physical disorders/ diseases is less consistent and inconclusive, possibly owing to methodological limitations inherent in studying these complex illnesses, or because psychological influences on immunity are not of the magnitude or type necessary to alter the body's response in these cases.

Hence, researcher intends to identify the gaps in the knowledge regarding the strong associations between psychological factors and diseases that do exists are attributable to immune changes and later, design and implement an intervention programme for improving the psychological and physical parameters influencing the immune system, subsequently promoting the better health environment.

3.3 Statement of the problem:

The proposed statement of the problem is: -

"A cross-sectional study of the impact of Positive Affect on Human Immunity through Cognitive Behavioural Therapy (CBT)"

3.4 Operational Definitions:

Table 1: Operational definitions

1.	**Cross- sectional**	*A research design that collects data from individuals of various stages of lifespan at a single point in time. (Scribrr, 2020)* In the proposed research will be conducted on the following age groups- i. Adolescents (13-18 years) ii. Young Adults (25-35 years) iii. Middle Adults (45-55 years)
2.	**Positive Affect**	*Positive affect refers to the extent to which an individual subjectively experiences positive moods such as joy, interest, and alertness.* (Lorenz T. et. al., 2022)
3.	**Immunity**	According to Encyclopedia of Biomedical Engineering (2019) *immunity is a complex biological system endowed with the capacity to recognize and tolerate whatever belongs to self, and to recognize and reject what is non-self.*
4.	**Cognitive- Behavioral Therapy (CBT)**	*A form of psychotherapy that focuses on the role of cognition in the expression of emotions and behaviours.* (Turner & Swearer, 2010) For the proposed study Cognitive Behavioural Therapy is **"an intervention method that aims to regulate the identified emotions (positive and negative) and their dysfunction by exploring and addressing how the integration of service users' thoughts, feelings and behaviours are contributing to the presenting physiological problem."**

3.5 Objectives:

The objectives of the proposed research are:

1. To assess the emotional state and causes of the fluctuations in the emotional state among sample.
2. To assess the baseline immunological profile and health of the sample.
3. To explore and implement the self- regulatory strategies and selecting components of Cognitive Behavioural Therapy (CBT) for developing positive affect among sample.
4. To study the effect of demographic profile and developed intervention strategies on emotional state, health, and immunological state of sample.
5. To correlate between the emotional state, health and immunity at baseline stage, pre-intervention stage, and post-intervention stage.
6. To obtain the feedback of intervention program, follow-up sustainability of the intervention strategies from the sample and disseminate the information for the future use.

3.6 Methodology:

3.6.1 Sampling Design:

3.6.1.1 Locale of the study:

Agra city will be conveniently selected as the locale of study.

3.6.1.2 Selection of Subject:

The researcher will purposively select three domains of health i.e., parapsychology, neuroendocrinology, and immunology. Thereafter will randomly select 150 individuals including both male and female from aforementioned domains of health. The sample will be distributed in two groups- Control group and Experimental group. Each group will contain 25 individuals in all the three respective domains of health.

Table 2: Distribution of sample across the domains of Health and Control and Experimental Group

S. No	Group/ Health domains	Para-psychology	Neuro-endocrinology	Immunology	TOTAL
1.	**Control group**	25	25	25	75
2.	**Experimental group**	25	25	25	75
	TOTAL	50	50	50	**150**

3.6.1.3 Selection Criterion of Subjects:

Individuals satisfying the following criteria will be selected for the study:

i. Individuals from following four developmental periods of lifespan will be selected as the sample-
   - Adolescence (ranging between the ages of 13 to 18 years) and
   - Adulthood-
     a. Early Adults (25 to 35 years),
     b. Middle Adults (45 to 55 years) and
     c. Late Adults (65 to 70 years)

ii. The sample will only include individuals suffering from para-psychological, neuro-endocrinological and immunological diseases.

iii. Individuals with stationary mild and moderate diseases conditions from aforementioned health domains already identified by the registered doctors of concerned field will be selected as the sample.

iv. Only those individuals will be included in the sample who have been taking treatment from at least 3 months by the registered doctors of concerned health domains.

v. Individuals with medication stability will be selected as the sample.

vi. Individuals under medication and no intervention will be the control sample while individuals with intervention along with the prescribed treatment will be the experimental sample.

Hence, researcher will select 150 individual, both adolescent and adults including male and female, falling in mild and moderate conditions of parapsychological, neuro-endocrinological and immunological diseases as sample.

3.6.1.4 Sampling Technique:

Random selection of the sample will be done through the registered doctors of concerned Health domain from Agra city.

3.6.2 Operational Design:

Operational design deals with the variables of the study, procedure of research and provides operational guidelines to attain the research objectives.

3.6.2.1 Variables:

- **Independent Variable**: Age, Gender, Height, Weight, Family Background, Occupation, Socio-economic Status, Family Medical History, Self- regulatory Activities, Cognitive Behavioural Technique.
- **Dependent Variable**: Positive Affect, Immunological markers, Neuro-endocrine markers, Emotion and Psycho-neuro-immunological (PNI) system interactions.

3.6.2.2 Procedure of the study:

To achieve the research objectives, the study will be conducted in five phases i.e. Exploratory phase, Pre-Intervention phase, Intervention phase, Post-Intervention phase, and Follow-up phase. Overview of each phase in given in Figure 1:

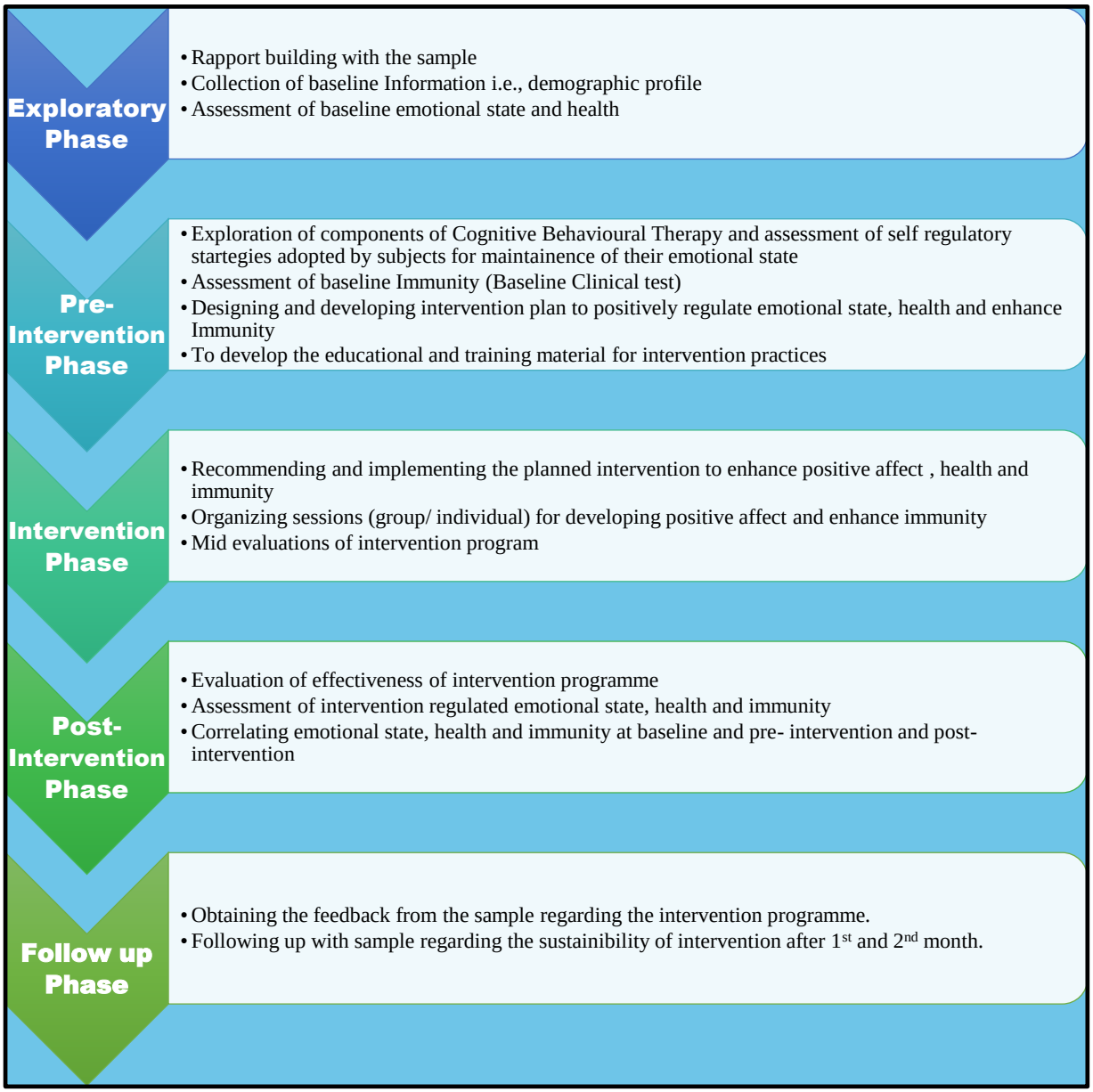
Exploratory Phase
• Rapport building with the sample
• Collection of baseline Information i.e., demographic profile
• Assessment of baseline emotional state and health
Pre-Intervention Phase
• Exploration of components of Cognitive Behavioural Therapy and assessment of self regulatory startegies adopted by subjects for maintainence of their emotional state
• Assessment of baseline Immunity (Baseline Clinical test)
• Designing and developing intervention plan to positively regulate emotional state, health and enhance Immunity
• To develop the educational and training material for intervention practices
Intervention Phase
• Recommending and implementing the planned intervention to enhance positive affect , health and immunity
• Organizing sessions (group/ individual) for developing positive affect and enhance immunity
• Mid evaluations of intervention program
Post-Intervention Phase
• Evaluation of effectiveness of intervention programme
• Assessment of intervention regulated emotional state, health and immunity
• Correlating emotional state, health and immunity at baseline and pre- intervention and post-intervention
Follow up Phase
• Obtaining the feedback from the sample regarding the intervention programme.
• Following up with sample regarding the sustainibility of intervention after 1st and 2nd month.

Figure 1: Phases of Research

3.6.2.2.1 Exploratory phase:

In this phase the researcher will visit the psychologists/ Psychiatrists, Endocrinologists/ Neurologists and Immunologists in order to collect the information of the individuals already identified as suitable sample referrals, followed by establishing rapport with the selected sample. Baseline information regarding demographic profile of the sample will be collected using General Information Performa, a checklist as research tool.

A self-constructed checklist will be used to assess the emotional state in control and experimental samples. In addition, a standardized questionnaire by Goods (1976) will be administered on sample to measure their perception of holistic health.

3.6.2.2.2 Pre-Intervention phase:

In the pre-intervention phase researcher will assess the baseline immunity through selected standardized clinical tests, performed by personnel's of the concerned health domain. The researcher will explore and decide the components of the intervention technique i.e., Cognitive Behavioural Therapy (CBT). Later, all the resources required for conducting activities under Cognitive Behavioural Therapy (CBT) in intervention period will be designed and organised in this phase. Researcher has already taken consent of sample regarding participation in intervention programme till this phase and thus workshops/ sessions of CBT will be arranged to prepare them for implementation of the various activities designed under CBT for proactively develop the positive affect, impacting their immune system and health gradually. Identification of resource persons/ experts for workshops/ session will be done respectively in this phase.

Subsequently, researcher will administer the checklist to assess the self- regulatory techniques adopted by the sample in order to maintain their emotional state. Additionally, a standardized "Emotional Intelligence Inventory" by Mangal & Mangal (2021) will also be administered on the sample.

3.6.2.2.3 Intervention phase:

This will be an action oriented phase; the expected duration of intervention phase will be of 18 weeks i.e., 4.5 months. The intervention duration will split into 6 sessions of Cognitive Behaviour Therapy. The main objective of intervention phase is to direct the sample individuals to engage into different techniques to enhance their emotional state impacting their immunity, thereby positively enhancing

their health. Sample for the study will be taken through the specialists from the selected health domain, i.e., para-psychology, Neuro-endocrinology and Immunology and will be divided into control and experimental samples. The experimental group consisting of total 75 individuals will only be participating in the intervention program. The Experimental group will be given the Cognitive Behavioural Therapy.

Cognitive Behavioural Therapy is a psychotherapy which will be given in order to gradually enhance the positive affect in the sample. The major techniques which will be adopted and given as a group/ individual intervention includes A-B-C (i.e., antecedents-behaviour-consequences) model and New belief/ Old belief system. The CBT will be given into 6 sessions in the entire tenure of intervention to the respective experimental groups. The duration of each session will be 60 minutes/week. Duration of the intervention session is subjected to the intensity of the disease and type of the activity recommended. The intense activities will take more than 60 minutes.

Table 3: Detail of intervention session

S.No.	Session	Duration	Objective
1	**Session 1:** Introduction	2 weeks	The practitioner and participant will work together to assess the identified stressor(s) and the participant's emotional state and to identify negative behaviours adopted. This part of the intervention included psycho-education and the development of mutual goals.
2	**Session 2:** Understanding the significance Self- care and Healthy Behaviours	2 weeks	Introduction to relaxation techniques and discussion about health behaviours
3	**Session 3:** Managing Behaviour	4 weeks	The practitioner will train the participant in relaxation and coping strategies. The discussions also included the identification of 'triggers' of unsafe health behaviours and their management.
4	Session 4: Regulating Emotions	2 weeks	Continuation of the suggested strategies to up regulate the emotions.
5	**Session 5:** Managing Immunity	4 weeks	Adaptation to new strategies to enhance the immunity and health outcomes.
6	**Session 6:** Consolidation and Relapse Prevention	4 weeks	The practitioner and participant will explore how to put the elements discussed into practice, consolidation, and discussion of long-term goals.

3.6.2.2.4 Post-Intervention phase:

The impact of the intervention program conducted in the intervention phase will be evaluated in the post- intervention phase. Tools used to assess the emotional state in the exploratory phase and clinical tests performed to assess the immunity along with Emotional Intelligence Inventory in pre-intervention stage will be re-administered to assess the regulated states of emotion and immunity in control and experimental samples. The researcher will try to measure the correlation between emotional state, health and immunity.

3.6.2.2.5 Follow up phase:

At the end of intervention phase, researcher will hand over a list of activities designed for pro-actively regulating the emotions, thereby enhancing immunity among sample. The list will include the individualised and personalized activities and a guide to follow and continue the activities. Researcher will also request individuals to inculcate CBT-based activities taught during the intervention phase as a part of their daily routine.

The feedback regarding suitability of intervention programme from the experimental sample will also be taken at this stage. Sustainability of activities to enhance immunity by up regulating the emotional state will be assessed via telephonic contact. Persistence of the up regulation of emotions and enhanced immunity among individuals after 1st and 2nd month will be assessed.

For the purpose of disseminating information researcher will develop a manual to develop the positive affect and enhance immunity among individuals suffering with para-psychological neuro-endocrinological and immunological diseases of mild and moderate conditions. Newspaper articles and pamphlets etc. will also be published to circulated information in mass population.

3.6.3 Observational Design:

3.6.3.1 Techniques of data collection:

Questionnaires, checklist, selected clinical tests, and Feedback form will be used for data collection in the present study.

3.6.3.2 Research Tool:

Self-constructed and/or adapted tools will be administered to fulfil the research objectives enlisted in table 3.

Table 4: List and details of the tools to be used in the proposed study.

Assessment and Evaluative Tools		
Name of the Tools	**Type of Tools**	**Administration of Tools**
Demographic Information Performa	Checklist (Self-constructed)	• Exploratory Phase
Understanding Emotions (Assessment of emotions and emotional state)	Checklist (Self-constructed)	• Exploratory Phase • Post- intervention Phase
Self- regulation of Emotions (self- regulatory strategies adopted to manage emotional dysregulation)	Checklist (Self-constructed)	• Pre- Intervention Phase
General Holistic Health Perception Questionnaire	Questionnaire (Standardized; Goods, 1976)	• Exploratory Phase • Post- Intervention Phase
Emotional Intelligence Inventory	Questionnaire (Standardized, Mangal & Mangal)	• Pre- Intervention Phase • Post- intervention Phase
Suitability of Intervention programme	Individual Feedback Form (Self-constructed)	Once during Post intervention phase
Clinical Tests (Assessment of Immunity) *		
Name of the Test	**Type of Test**	**Administration of tools**
1. Blood Pressure 2. Resting Pulse Rate	General Physical Parameters	• Pre- Intervention Phase • Post- Intervention Phase
1. CBC (Complete Blood Count) 2. DLC (Differential Leucocyte Count)	Blood Count	
1. Adrenaline Level 2. Cortisol Level 3. C-Reactive Protein Level	Hormonal Profile	
1. Vitamin D 2. Vitamin B12	Vitamin Profile	
1. IgA profile 2. IgE profile 3. IgM profile	Immunological Assay	
Training Material		
Name of the Tools	**Type of Educational Tools**	
Activity kit	• Real Objects • Audio-video aids	
Workshop	• PPT • Demonstration	
Information Materials	• Pamphlet • Manual • News Article	

(*The *cost of suggested clinical tests will either be bore by the researcher through researcher's parent institution funds or via funds from research projects***.)**

3.6.4 Statistical Design:

The information collected will be analysed with the help of following tables and statistical tools respectively.

- Frequency
- Percentage
- Arithmetic Mean
- Standard Deviation
- Z-test
- Correlation

Further analysis of data will be determined on the basis of type and nature of data obtained.

3.7 Delimitations of the study:

- The proposed research will be a single researcher study.
- Though the study is a cross-sectional research but infants and children will be excluded from the sample.
- Individuals aging above the adolescence will be included in the sample.
- Individuals with serious and moribund chronic psychological or physical illness will be excluded from the sample.
- Individuals taking Vitamin D and B-12 supplements will not be chosen as sample
- The present study will only be conducted in Agra city and is not a multicentre trial.

SECTION- IV

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